DEC 2 6 2013

KINGTECH ENTERPRISES LIMITED

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TEL : 852-24810188 FAX : 852-24253939

510(K) SUMMARY

for KINGTECH Digital Thermometer, TT1001

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(K) number is: K 133111

Submission Date:	September 21, 2013
Submitter:	Kingtech Enterprises Limited Room 2016, 20/F., Block B, Regent Center 70 Ta Chunen Ping Street, Kwai Chung, New Territories, HK Tel: +852-24810188 Fax:+852-2423939
Manufacturer:	Kingtech (Dong Guan) Enterprises Limited Farm Village, Da Ling Shan Town, DongGuan, China Tel: +86-76985636260 Fax:+86-76985636350
Establishment Registration No.:	3008808166
Official Contact:	Dr. Jen, Ke-Min Tel: +886-3-5208829 Fax:+886-3-5209783 Email: ceirs.jen@msa.hinet.net
Common / Usual Name:	Digital Thermometer
Trade Name:	KINGTECH Digital Thermometer, TT1001
Classification Code:	FLL, Class II, 21 CFR 880.2910
Intended Use:	TT1001 Digital Thermometer is intended to measure the body temperature orally and to be used by medical professionals in clinical and hospital environments and consumers in a home environment. It is intended for use on people of all ages.
Predicated Devices:	K122520, TaiDoc Digital Thermometer, TD-1001 TaiDoc Technology Corporation
Device Description:	The Digital Thermometer TT1001 enables easy and accurate readings over the body temperature range. It must be used in conjunction with disposable probe cover when taking temperature. From the construction point of view, the digital thermometer comprises of a thermistor for measuring sensor, a reference resistor for comparison of temperature, a buzzer for sounding effect, an ASIC for calculating, and LCD for displaying the measuring temperature digitally for which the thermistor contacts.

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Test Principle:

The Digital thermometer TT1001 is the electronic thermometer operated by a thermistor as the temperature sensor and an ASIC (Application Specified IC) for signal processing. The basic operation principle is that a change of thermistor, caused by changes of temperature, provide signal to ASIC. ASIC gets the sensor's signal then processes the signal and calculates the result, after that displays the temperature result by a LCD.

Performance Tests:

Safety Test:

- IEC 60601-1 – Medical electrical equipment Part 1. General requirements for safety, 2005.

Electromagnetic Compatibility Test:

- EN/IEC 60601-1-2 – Medical electrical equipment, Part 2. Electromagnetic compatibility – Requirements and tests, 2007.

Biocompatibility Tests:

- ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for in irritation and skin sensitization.

Clinical Tests:

In accordance with:

EN12470, ASTM E 1965-98, and ASTM E1112-00

Comparison and Conclusion:

This 510k submission only need change the application name of the predicate K122520 from "TaiDoc Digital Thermometer, TD-1001" to "KINGTECH Digital Thermometer, TT1001"; there is the entire identical specifications and only need to separate into different 510k. And all of the test reports and documentation for this 510k submission were prepared by TaiDoc Technology Corporation and BioCare Co., Ltd. who is a branch office of TaiDoc Technology Corporation.

Thus the new device is substantially equivalent to the predicate devices in this aspect.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 26, 2013

Kingtech Enterprises Limited
C/O Dr. Ke-Min Jen
Official Correspondent
Room 2016, 20/F., Block B, Regent Center
70 Ta Chunen Ping Street
Kwai Chung, New Territories
HONG KONG

Re: K133111
Trade/Device Name: KINGTECH Digital Thermometer TT1001
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 21, 2013
Received: September 30, 2013

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer
-S for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133111

Device Name
KINGTECH Digital Thermometer, TT1001

Indications for Use *(Describe)*
TT1001 Digital Thermometer is intended to measure the body temperature orally and to be used by medical professionals in clinical and hospital environments and consumers in a home environment. It is intended for use on people of all ages.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Digitally signed by Richard C. Chapman
Date: 2013.12.26 11:36:46 -05'00'

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